

WHAT IS CLAIMED IS:

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1. A cleavable signal element, comprising:
a cleavable spacer, said cleavable spacer having a
substrate-attaching end, a signal-responsive end, and a
cleavage site intermediate said substrate-attaching end
and said signal responsive end;
a signal responsive moiety;
a first side member adapted to bind a first site on
a chosen analyte; and
a second side member adapted to bind a second site
of said chosen analyte;
wherein said signal responsive moiety is attached to
said cleavable spacer at said signal responsive end,
said first side member is attached to said cleavable
spacer intermediate said signal responsive end and said
cleavage site, and said second side member is attached
to said cleavable spacer intermediate said cleavage site
and said substrate attaching end.
2. The cleavable signal element of claim 1, wherein said
signal responsive moiety is adapted to reflect or
scatter incident light.
3. The cleavable signal element of claim 2, wherein said
signal responsive moiety is a metal microsphere.
4. The cleavable signal element of claim 3, wherein said
metal microsphere consists essentially of a metal
selected from the group consisting of gold, silver,
nickel, platinum, chromium and copper.
5. The cleavable signal element of claim 4, wherein said
metal microsphere consists essentially of gold.
6. The cleavable signal element of claim 5, wherein said
gold microsphere has a diameter between 1 nm - 10 μ m.

7. The cleavable signal element of claim 6, wherein said gold microsphere has a diameter between ~~0.5~~ - 5 μm .
8. The cleavable signal element of claim 7, wherein said gold microsphere has a diameter between 1 - 3 μm .
9. The cleavable signal element of claim 1, wherein said cleavage site is susceptible to chemical cleavage.
10. The cleavable signal element of claim 9, wherein said chemically susceptible cleavage site includes at least one siloxane group.
11. The cleavable signal element of claim 1, wherein said first side member and said second side member include oligonucleotides.
12. The cleavable signal element of claim 11, wherein said first and second side member oligonucleotides are 5mers - 20mers.
13. The cleavable signal element of claim 12, wherein said first and second side member oligonucleotides are 8mers - 17mers.
14. The cleavable signal element of claim 12, wherein said first and second side member oligonucleotides are 8mers - 12mers.
15. The cleavable signal element of claim 1, wherein said first side member includes a first member of a first specific binding pair, said second side member includes a first member of a second specific binding pair, and said second member of said first specific binding pair and said second member of said second specific

binding pair are each present on the surface of a single analyte.

16. The cleavable signal element of claim 15, wherein said
5 first member of said first specific binding pair includes a first antibody, antibody fragment, or antibody derivative, and said first member of said second specific binding pair includes a second antibody, antibody fragment, or antibody derivative.
- 10 17. The cleavable signal element of claim 15, wherein
said first side member includes a first side member oligonucleotide,
said second side member includes a second side
15 member oligonucleotide,
said first member of said first specific binding pair includes a first binding pair oligonucleotide,
said first member of said second specific binding pair includes a second binding pair oligonucleotide, and
20 said first side member oligonucleotide includes sequence complementary to sequence included in said first binding pair oligonucleotide, said second side member oligonucleotide includes sequence complementary to sequence included in said second binding pair
25 oligonucleotide, and said complementary sequences are noncovalently associated.
18. An assay device, comprising:
a solid support substrate, and
30 a plurality of cleavable signal elements according to claim 1,
wherein said cleavable signal elements attach through their substrate-attaching ends to said solid support substrate in a spatially addressable pattern.
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19. An assay device, comprising:
a solid support substrate, and
a plurality of cleavable signal elements according
to any one of claims 2 - 17,
5 wherein said cleavable signal elements attach
through their substrate-attaching ends to said solid
support substrate in a spatially addressable pattern.

20. The assay device of claim 18, wherein said solid support
10 substrate is a plastic selected from the group
consisting of polypropylenes, polyacrylates, polyvinyl-
alcohols, polyethylenes, polymethylmethacrylates and
polycarbonates.

15 21. The assay device of claim 20, wherein said solid support
substrate is polycarbonate.

22. The assay device of claim 18, wherein said solid support
20 substrate is fashioned as a disk.

23. The assay device of claim 22, wherein said disk has an
outer diameter of about 120 ~~mm~~ and a thickness of about
1.2 mm.

25 24. The assay device of claim 18, wherein said signal
responsive moiety of each of said cleavable signal
elements is ferromagnetic.

25. The assay device of claim 18, wherein
30 said first side member includes a first antibody,
antibody fragment, or antibody derivative, and
said second side member includes a second antibody,
antibody fragment, or antibody derivative.

26. The assay device of claim 25, wherein
said first antibody and said second antibody are
specific for different epitopic sites of a virus
selected from the group consisting of human
immunodeficiency viruses, hepatitis A, hepatitis B,
hepatitis C, and human herpesviruses.
27. The assay device of claim 26, wherein said first
antibody and said second antibody are specific for
epitopes of a human immunodeficiency virus.
28. The assay device of claim 27, wherein said
immunodeficiency virus is HIV-1.
29. The assay device of claim 27, wherein said
immunodeficiency virus is HIV-2.
30. The assay device of claim 26, wherein said virus is
hepatitis C.
31. The assay device of claim 18 which includes, in said
plurality, signal elements adapted to recognize distinct
analytes.
32. The assay device of claim 18, wherein the spatial
pattern of signal elements signals concentration of one
or more analytes.
33. The assay device of claim 18, further comprising
computer software encoded upon the support substrate.
34. An assay method comprising the steps of:
contacting the assay device of claim 18 with a
liquid sample,
contacting said assay device with a cleaving agent
adapted to cleave said plurality of attached cleavable
signal elements,

removing signal responsive ends of said cleaved
signal elements, and

detecting the presence of the signal responsive
moiety of analyte-restrained cleaved signal elements
adherent to the solid support substrate.

35. An assay method comprising the steps of:

contacting the assay device of claim 19 with a
liquid sample,

contacting said assay device with a cleaving agent
adapted to cleave said plurality of attached cleavable
signal elements,

removing signal-responsive ends of said cleaved
signal elements, and

detecting the presence of the signal responsive
moiety of analyte-restrained cleaved signal elements
adherent to the solid support substrate.

36. The assay method of claim 34, wherein said signal
elements comprise one or more siloxane moieties and said
cleavage agent includes sodium fluoride.

37. The assay method of claim 36, wherein said cleavage
agent includes 1 mM to 1 M sodium fluoride.

38. The assay method of claim 36, wherein said cleavage
agent includes 50 mM to 500 mM sodium fluoride.

39. The assay method of claim 36, wherein said cleavage
agent includes sodium fluoride at about 100 mM.

40. The assay method of claim 34, further comprising one or
more washing steps.

41. The assay method of claim 34, further comprising the
step of rotating said assay device.

42. A nucleic assay hybridization assay, comprising the steps of:

contacting the assay device of claim 18 with a liquid sample containing nucleic acids, wherein the first side member and the second side member of at least one of said attached signal elements each includes an oligonucleotide,

contacting said assay device with a cleaving agent adapted to cleave said plurality of attached cleavable signal elements,

removing signal responsive ends of said cleaved signal elements, and

detecting the presence of the signal responsive moiety of analyte-restrained cleaved signal elements adherent to the solid support substrate.

43. A nucleic assay sequencing method, comprising the steps of:

contacting the assay device of claim 18 with a liquid sample containing nucleic acid, wherein the first side member and the second side member of each of said attached signal elements includes an oligonucleotide,

contacting said assay device with a cleaving agent adapted to cleave said plurality of attached cleavable signal elements,

removing signal responsive ends of said cleaved signal elements,

detecting the presence of the signal responsive moiety of analyte-restrained cleaved signal elements adherent to the solid support substrate,

wherein the spatially addressable pattern of side member oligonucleotide sequences permits calculable reconstruction of contiguous sequence from signal response.

44. An immunoassay, comprising the steps of:

contacting the assay device of claim 18 with a liquid sample containing antigenic analytes, wherein the first side member and the second side member of at least one of said attached signal elements each includes an antibody, antibody fragment, or antibody derivative,

contacting said assay device with a cleaving agent adapted to cleave said plurality of attached cleavable signal elements,

removing signal responsive ends of said cleaved signal elements, and

detecting the presence of the signal responsive moiety of analyte-restrained cleaved signal elements adherent to the solid support substrate.

45. The immunoassay of claim 44, wherein said first and said second antibody each recognizes an epitopic site of a virus selected from the group consisting of human immunodeficiency viruses, hepatitis A, hepatitis B, hepatitis C, and human herpesviruses.

46. The immunoassay of claim 45, wherein said virus is a human immunodeficiency virus.

47. The immunoassay of claim 46, wherein said virus is HIV-1.

48. The immunoassay of claim 46, wherein said virus is HIV-2.

49. The immunoassay of claim 45, wherein said virus is hepatitis B.

50. The immunoassay of claim 45, wherein said virus is hepatitis C.

~~52~~⁵⁷. The immunoassay of claim 45, wherein said virus is a human herpesvirus.

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